UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SERONO, INC. and INDUSTRIA FARMACEUTICA SERONO SpA, Plaintiffs, v. FERRING PHARMACEUTICALS, INC., Defendant.	**ANSWER AND COUNTERCLAIM** Civil Action No. 04-10305 MLW

Ferring Pharmaceuticals, Inc. ("Ferring") hereby answers the Complaint of plaintiff Serono, Inc. and Industria Farmaceutica Serono SpA ("Serono").

Ferring admits, denies, states, and alleges as follows:

As to the introductory part of the Complaint which appears before the numbered paragraphs and allegations therein, Ferring admits that Serono appears to be the patent holder with respect to certain technologies relating to infertility, that the patent rights at issue in this lawsuit cover pharmaceutical hormone compositions and therapeutic regimens that are used for ovulation induction and *in vitro* fertilization, but denies the remaining statements found in the introductory paragraph.

JURISDICTION AND PARTIES

1. As to the allegations in paragraph 1, admits.

2. As to the allegations in paragraph 2, admits.

3. As to the allegations in paragraph 3, admits.

4. States that it is without sufficient knowledge and information to form a belief as to the truth of the allegations in paragraph 4.

5. As to the allegations in paragraph 5, admits.

FACTUAL BACKGROUND

6. Admits that on February 16, 1988, the United States Patent and Trademark Office appears to have issued a patent under Patent No. 4,725,579 ("the '579 patent") to Serono; states that a copy of the '579 patent is attached to the Complaint as Exhibit A and that the '579 patent covers certain ratios of hormones as listed in the claims; except as so admitted and stated, denies the allegations in paragraph 6.

7. Admits that on June 16, 1998, the United States Patent and Trademark Office appears to have issued to the specified Serono entity a patent under Patent No. 5,767,067 (the '067 patent"); states that a copy of the '067 patent is attached to the Complaint as Exhibit B and that the '067 patent covers certain hormone preparations as listed in the claims; except as so admitted and stated, denies the allegations in paragraph 7.

8. Admits that the co-inventors on the '579 patent appear to be Drs. Howard and Georgiana Jones, and that said persons have worked in the infertility field for many years; states that it is without sufficient knowledge and information to form a belief as to the truth of the allegations regarding the sponsorship of research with respect to infertility, the techniques that are used in clinics and hospitals throughout the world today, the ratios of hormones which substantially improve the pregnancy rate of patients overall; except as so admitted and stated, denies the allegations in paragraph 8.

9. Admits that FSH preparations can be made by purifying hormones from women's urine, that prior art compounds, including Serono's Metrodin®, contained FSH together with LH and significant amounts of other urinary proteins, that certain immunoassay standards are

described in the '067 patent; states that it is without sufficient knowledge and information to form a belief as to the funding of the research conducted in-house at Serono, if any, and whether subcutaneous administration of highly purified FSH was highly desirable; except as so admitted and stated, denies the allegations in paragraph 9.

10. Admits that Serono sells pharmaceutical products containing FSH and/or mixtures of FSH and LH, that Ferring sells products containing FSH and/or mixtures of FSH and LH called Bravelle® and Repronex®; states that the '579 patent apparently expires on February 21, 2005; except as so admitted and stated, denies the allegations in paragraph 10.

11. Admits that the '067 patent apparently expires on March 30, 2015 and that Ferring has described Bravelle® as a purified, human-derived FSH which contains certain amounts of LH; states that the partial quotation attributed to Ferring's President, Wayne Anderson, was made to contrast Bravelle® with recombinant technology, which had no meaningful advantage over the human-derived hormones found in Bravelle® both in terms of efficacy and safety; except as so admitted and stated, denies the allegations of paragraph 11.

12. Admits that Dr. Dennis Marshall co-authored the referenced article in Today's Therapeutic Trends, further alleging in that regard that the bioactivities for FSH and LH in the mixed preparations reported therein were compared with the actual bioactivities in the starting preparations therein, rather than the bioactivities set forth in the product label; except as so admitted and stated, denies the remaining allegations of paragraph 12.

13. As to the allegations in paragraph 13, denies.

14. Admits that the quoted portion of the Ferring product insert appears to be accurate; alleging further in that regard that the allegations relating to claims and coverage of products is

subject to claim construction; except as so admitted and alleged, denies the allegations in paragraph 14.

15. Admits that Ferring has sponsored various research where mixed protocols are discussed, including the article referenced and that various ratios are discussed in said protocols; except as so admitted, denies the allegations in paragraph 15.

16. Admits that Ferring from time to time issues press releases such as those referenced in paragraph 16, states that it presents data relating to various clinical trials, and that those data are presented at meetings of practitioners that deal with infertility; except as so admitted and stated, denies the allegations in paragraph 16.

FIRST COUNT
(Infringement of the '579 Patent)

17. Repeats and realleges the responses to paragraph 1 through 16 as though set forth in full herein.

18. As to the allegations in paragraph 18, denies.

19. As to the allegations in paragraph 19, denies.

20. As to the allegations in paragraph 20, denies.

SECOND COUNT
(Infringement of the '067 Patent)

21. Repeats and realleges the responses to paragraph 1 through 20 as though set forth in full herein.

22. As to the allegations in paragraph 22, denies.

23. As to the allegations in paragraph 23, denies.

24. As to the allegations in paragraph 24, denies.

AFFIRMATIVE DEFENSES

1. Ferring does not infringe, and at all times relevant to this action, has not infringed any valid or enforceable claim of the ’067 and/or ‘579 patents, either literally or under the doctrine of equivalents, nor contributed to infringement by others, nor actively induced others to infringe, any claim of any of the patents-in-suit.

2. The ’067 and/or ‘579 patents are invalid and/or unenforceable for failing to comply with Title 35 of the United States Code, including but not limited to, one or more of the provisions of 35 U.S.C. §§ 101, 102, 103, and 112.

3. Serono is precluded from claiming damages against Ferring for acts occurring more than six years prior to the filing of the Complaint pursuant to 35 U.S.C. § 286.

4. During the prosecution of the ’067 and/or ’579 patents, various arguments and amendments were made in order to achieve allowance of the claims of the patents at issue. These arguments and amendments limit the scope of the claims of the ’067 and/or ‘579 patents. These limitations render use of Ferring’s products outside the scope of the claims of the patents-in-suit under the doctrine of prosecution history estoppel.

5. The ’067 and/or ‘579 patents are unenforceable under the doctrine of prosecution history laches because of the unreasonable and unnecessary delay during the prosecution of the patents-in-suit that prejudiced intervening adverse public rights.

6. The ’067 and/or ‘579 patents are unenforceable against Ferring because of Serono’s unclean hands.

7. Serono’s claims for infringement are barred by the equitable doctrine of estoppel.

8. Serono’s claims for damages are barred by the equitable doctrine of laches.

9. The ‘067 and ‘579 patents are unenforceable because they are part of a family of patents which are tainted by the procurance of United States Patent No. 4,589,402 (“the ‘402

patent"). The '402 patent is unenforceable because it was obtained through inequitable conduct by the inventor, Georgeanna S. Jones; the attorney prosecuting the patent application, Edward A. Meilman, or anyone else substantively involved in the prosecution of the patent application, because Georgeanna S. Jones, Edward A. Meilman or anyone else substantively involved in the prosecution of the patent application withheld and misrepresented information material to examining the patent application with the intent to deceive or mislead the United States Patent and Trademark Office in violation of their duty of candor as required by 21 C.F.R. §1.56. Georgeanna S. Jones, Edward A. Meilman or anyone else substantively involved in the prosecution of that '402 patent application knew or should have known of at least the following reference(s) which is material to the examination of the '402 patent application: Schoemaker, et al., "Stimulation of follicular growth with "pure" FSH in patients with anovulation and elevated LH levels", Obstetrics and Gynecology Vol. 51, No. 3 p. 270-277 (March 1978). The Schoemaker reference was co-authored by Georgeanna S. Jones. Although Georgeanna S. Jones, Edward A. Meilman or anyone else substantively involved in the prosecution of that '402 patent application knew or should have known of the Schoemaker reference, the reference was withheld from the United States Patent and Trademark Office with the intent to deceive or mislead. In addition to intentionally withholding material information, Georgeanna S. Jones, Edward A. Meilman or anyone else substantively involved in the prosecution of the patent application also misrepresented information material to examination of the '402 patent application, including, at least the following statements made during prosecution of that patent application:

> Donini has been cited to show the use of HCG for ovulation induction. The use of HCG to induce ovulation of follicles which have been matured is known. However, the use of HCG to induce ovulation of follicles which have been matured to a course of treatment which involves administering exogeneous FSH in the absence of exogeneous LH is new.

Prosecution History, Amendment under Rule 115 dated October 15, 1985 p. 2

> Those skilled in the art would not recognize that a reference [in the Seed reference] to the administration of FSH meant the administration of this hormone alone without LH in the absence of an explicit statement in the reference to this effect. Since there is no such statement in Seed, those skilled in the art would understand the reference to administration of FSH on page 23 to mean the administration of FSH together with LH. Prior to the present invention, those skilled in the art did not recognize that exogeneous FSH could be administered in the absence of exogeneous LH.

Amendment under Rule 115 dated October 15, 1985, at p. 3. Contrary to the statements made by the applicants, it was well known to those skilled in the art at the time of filing the '402 patent application that exogeneous FSH could be administered in the absence of exogeneous LH. In fact, the published Schoemaker reference disclosed nearly seven years prior to the filing of the '402 patent application that:

> Induction of ovulation with an FSH preparation virtually devoid of LH might therefore reduce the incidence of hyperstimulation in this group. This paper describes our first results with stimulation of follicular growth with pure FSH and subsequent induction of ovulation with hCG in patients with elevated LH levels.

Schoemaker, at 270. The inventor, Georgeanna S. Jones, is a co-author of the Schoemaker reference and knew or should have known that the statements made during prosecution that the administration of FSH in the absence of exogeneous LH is new or was unknown to those skilled in the art prior to the present invention were false. Further, the patent attorney prosecuting the '402 patent application, Edward A. Meilman or anyone else substantively involved in the prosecution of that '402 patent application knew or should have known that the above statements made during prosecution were false. By reason of the foregoing, the '402 patent and the patents in suit are unenforceable.

COUNTERCLAIM

THE PARTIES

1. Serono, Inc. has pleaded that it is a Delaware corporation having a principal place of business at One Technology Place, Rockland, Massachusetts 02370.

2. Ferring Pharmaceuticals, Inc. is a Delaware corporation with a principal place of business at 400 Rella Boulevard, Suffern, New York 10901.

3. Serono, Inc. has pleaded that a related company is (and has been) an innovator of new and important discoveries for treating female infertility and that the related company had total worldwide sales in 2001 above $1 billion, with approximately $600 million of those sales in fertility treatment products. Ferring is informed and believes that this related company is Serono, Inc.'s parent company, Serono S.A. having a principal place of business at 15 Bis Chemin Des Mines Case Postale 54, CH-1211 Geneva 20, Switzerland V8. Serono S.A. has enaged in the anticompetitive acts described further below through a number of operating companies which it owns or controls, including without limitation Serono, Inc. and Industria Farmaceutica Serono SpA, which are referred to herein collectively as "Serono."

JURISDICTION AND VENUE

4. This action arises under the patent laws and antitrust laws of the United States of America. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337 and 1338(a). This Court also has jurisdiction pursuant to 28 U.S.C. § 1332 based upon the diversity of the citizenship of the parties.

5. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

6. All of the acts complained of relating to the antitrust laws of the United States as alleged herein relate to activities that have and are continuing to occur in the United States. The relevant geographic market is the United States.

GENERAL ALLEGATIONS

7. Serono is the dominant company in the United States market for infertility treatment of female patients. Serono holds itself out as an innovator in the field of infertility and is the largest company in the world that participates in said market. Serono has been dominant in the infertility market since the 1970s. Serono's worldwide sales in 2001 were approximately $2 billion, with approximately $600 million of sales in the infertility market.

8. Ferring is a recent entrant into the infertility prescription drug market in the United States. Serono remains a dominant force with market power in the infertility prescription drug market, distinct submarkets of said infertility prescription drug market, and is seeking to extend its dominance into other infertility markets, as more particularly described below.

9. Over the past thirty years, the infertility prescription drug market in the United States has evolved from treating patients with synthetic drugs to the use of gonadotropin drugs. Prior to 1969, synthetic drugs were used to stimulate the hypothalamus to release more gonadotropin releasing hormone (GnRH), which then prompted the pituitary to release more luetenizing hormone (LH) and follicle stimulating hormone (FSH), and thus increased the stimulation of the ovary to begin to produce a mature egg. In contrast, today's gonadotropin therapies involve directly adding exogenous FSH, LH, or human chorionic hormone (hCG) to stimulate the ovary to produce a mature egg.

10. The market for gonadotropins includes a number of distinct relevant submarkets. These submarkets of gonadotropins can be separated into various groups including: urinary

derived human FSH and LH, urinary derived human FSH, recombinant FSH, urinary derived hCG and recombinant hCG.

a. Urinary derived human FSH and LH are gonadotropin products that are extracted from the urine of postmenopausal women and contain both FSH and LH in varying ratios.

b. Urinary derived human FSH is a gonadotropin product that is extracted from the urine of postmenopausal women and purified in a manner so that FSH is present.

c. Recombinant FSH is a gonadotropin product that is manufactured using recombinant DNA technology resulting in an FSH product.

d. Urinary derived hCG is a gonadotropin product that may be derived from the urine of post-menopausal women.

e. Recombinant hCG is a gonadotropin product that is manufactured using recombinant DNA technology.

11. Serono has been active in the United States infertility market since 1969 when it received approval from the Federal Drug Administration (FDA) to market a drug to treat female infertility. This drug was marketed in the United States as Pergonal®. Pergonal® is a gonadotropin product containing urinary derived human FSH and LH in approximately a 1:1 ratio.

12. In about the 1984 time period, Serono devised a plan to fraudulently secure a patent (the ‘402 patent) which would allow it to exclude competition in the market for FSH products. From 1969 to 1984, Serono had the entire gonadotropin market to itself. This allowed Serono to charge exorbitant prices. Fearing that it would lose its total dominance, Serono began

to reposition the market in the 80's by suggesting to customers that LH was not necessary for the treatment of female infertility and therefore an FSH product alone would be superior in treating female infertility.

13. Serono has unlawfully used its patent estate to maintain its dominant position in the infertility prescription drug market. Specifically, Serono has asserted and continues to assert patents against its competitors that Serono knew or should have known were procured by or tainted by fraud on the United States Patent and Trademark Office. Serono's assertion of a fraudulently procured patent is part of Serono's plan to exclude competition in the market for the use of FSH products alone. Affirmative defense nine, referenced above, is incorporated herein by reference.

14. Serono's fraud in connection with the '402 patent as alleged above, renders the patents in suit unenforceable based on Serono's unclean hands and its conduct with respect to the market for FSH products, and the subsequent procurement of the patents in suit.

15. In 1986, Serono received approval from the FDA to market another drug to treat female infertility. This drug was marketed in the United States as Metrodin®. Metrodin® is a gonadotropin product containing urinary derived human FSH and LH. Unlike Pergonal®, however, Metrodin® contained approximately 1 IU LH to 75 IU FSH (approximately 1.6% LH).

16. Metrodin® was discontinued in the United States shortly after Serono introduced Fertinex®. Fertinex® was approved by the FDA in 1996. Fertinex® is a highly purified urinary derived human FSH product. There is less than 0.1 IU LH per 1000 IU FSH in Fertinex®.

17. In addition to the gonadotropin market and the various submarkets discussed above, Serono also participates in other infertility prescription drug markets related to gonadotropin therapies. For example, GnRH antagonists are used in conjunction with

gonadotropin products to treat female infertility. Serono markets a GnRH antagonist under the trade name Cetrotide®. Similarly, Serono also markets hCG products under the trade names Profasi® and Ovidrel®, that are used in conjunction with gonadotropin therapies. Serono has used its dominate market power in gonadotropin markets to gain market share and at times dominate relevant submarkets such as the antagonist and recombinant hCG markets.

18. Serono held the entire market for urinary derived human FSH products to itself from 1986 to 1996, when it again repositioned the market to convince customers that recombinant FSH was the best treatment protocol for infertility.

19. In 1997, Serono received approval from the FDA to market the first recombinant FSH product to treat female infertility. This drug was marketed in the United States as Gonal-F®. Because Gonal-F® is a recombinant product, there is no LH present.

20. Serono has dominated the recombinant FSH market since 1997. This total dominance of the recombinant FSH market and market power therein, has allowed Serono to charge exorbitant prices in said market.

21. Serono sought to manipulate demand in the recombinant FSH market by creating an artificial shortage of its prescription drug infertility products, Pergonal® and Metrodin®. These actions were taken by Serono in an effort to thwart competition and to prime the market for receipt of its recombinant FSH product, Gonal-F®.

22. In addition, as Ferring was attempting to enter the infertility market with its own urinary derived human FSH and LH product, Repronex®, Serono again attempted to thwart competition by filing an unwarranted lawsuit against the FDA to enjoin the FDA from approving Ferring's application to market the product. At the time that the lawsuit was filed, Serono knew or should have known that, given the totality of all circumstances, including Serono's dominant

market share in the gonadotropin market and its fraudulent procurement of a patent, the litigation was objectively baseless, especially in view of the intent of Congress which passed laws to make generics and the approval process quicker and easier. The litigation was a part of Serono's plan to block competition from reaching the market rather than any legitimate concern about safety.

23. In an effort to thwart competition further and erect barriers to entry into the gonadotropin market and its various submarkets, Serono has engaged in the conduct of charging exorbitantly high non-market prices for some products and at the same time engaging in predatory pricing in other products. For example, in the recombinant FSH market, where Serono faces little or no competition, Serono's prices are very high. In contrast, markets in which Serono faces some competition, e.g., the urinary derived human FSH and LH market, Serono charges below cost prices by giving Pergonal® away to its customers free of charge. Meanwhile, Serono uses its market power to control and maintain exorbitantly high prices of its recombinant FSH product.

24. Certain of Serono's infertility prescription drugs are marketed jointly, so that a relevant market can be considered to be a cluster of said drugs and infertility services which, when taken together, give Serono added market power and dominance in said cluster. Because of the way that Serono promotes these clustered products and services, in a bundled fashion, Serono has leveraged its advantages in one market to gain an unfair advantage in other markets. Serono's conduct in that regard has resulted in actual monopolization and attempted monopolization of various clustered markets, including the market of FSH products clustered with FSH/LH combinations.

25. Serono has also engaged in sending letters to customers regarding lawsuits Serono has filed against its competitors. Attached hereto as Exhibit 1 are true and correct copies of

letters sent by Serono to customers. Rather than competing in the marketplace on the merits, Serono engaged in this behavior with the intent of influencing the customer's purchasing decisions and harming its competitors' ability to market competing products. Serono's actions, as described above, have created additional barriers to entry into the market and have had the effect of stifling competition.

26. Serono has continued to hold a dominant position in the infertility prescription drug market through various anticompetitive conduct. Serono knew that without such anticompetitive conduct, a greater number of actual and potential competitors would enter the market.

27. Serono knew that without a plan to protect itself from competition, it would be forced to charge lower prices for its products and services, with resultant smaller profit margins and a decrease in Serono's earnings.

28. Beginning in the 1990s, and continuing to the present, Serono developed and implemented a series of actions to shield itself from competition. These actions included the following major components:

a. Survey competitive products and determine the strongest competitors;

b. Block competitors' products from reaching the market through opposition to said products during the regulatory process;

c. Exclude other competitive products from the United States infertility prescription drug market and relevant submarkets, by threatening and instituting lawsuits against competitive companies;

d. Promote the use of Serono's infertility prescription drug products by unrestricted payments, grants and gratuities to health care providers; and

e. Promote the use of Serono's infertility prescription drug products by incentive payments, grants and gratuities to drugstores.

29. Serono knew that it could accomplish its plan by using its dominance and market power in the infertility prescription drug market to gain, maintain, and increase its dominance in distinct submarkets of said market.

30. Serono's anticompetitive plan has been accomplished through various predatory acts, including but not limited to the following:

a. Providing large unrestricted grants and subsidized advertising to infertility specialists to motivate them to refrain from prescribing competitors' infertility products in favor of Serono's infertility products;

b. Promoting its infertility products by giving away free goods to health care providers;

c. Selling infertility products at or below cost with the purpose of driving competitors out of the infertility prescription drug market, with the ultimate goal of recoupment of revenues after the competitors have left the market;

d. Entering into exclusive relationships with third parties with the purpose and effect of excluding competitors from the infertility prescription drug market;

e. Providing undue and unreasonable pressure on prescribers of Serono's infertility prescription drug products to favor Serono's products to the exclusion of competitive products by suggesting to said prescribers that unrestricted grant money would be withdrawn;

f. Instituting unwarranted litigation against Serono's competition to force said competitive products off the market;

g. Providing excessive rebates, allowances, free goods and/or discounts to pharmacy providers to encourage them to sell Serono's infertility products to the exclusion of competitors' products;

h. Providing excessive discounts and/or rebates to purchasers with the intent of excluding competitors' products;

i. Engaging in price discrimination with respect to infertility products;

j. Manipulating the distribution network for infertility products through use of its Strategic Business Expansion Unit program and Strategic Practice Expansion Unit program;

k. Notifying providers about patent infringement suits with the goal of displacing competitors' infertility prescription drug products from the market;

l. Using its patent estate to restrict competition and control prices; and

m. Providing cash payments to infertility specialists and their staff for prescribing Serono's infertility products and to motivate them to refrain from prescribing competitors' infertility products.

31. Many of said predatory acts are of questionable legality under applicable state fraud and abuse laws and further evidence Serono's anticompetitive behavior in view of Serono's dominate market share and market power.

32. All of said predatory acts have been part of Serono's plan to exclude competition and control prices in the infertility prescription drug market, with a corresponding increase in Serono's profit margins.

33. Serono's profit margins have increased dramatically over the last several years, due in part, to the anticompetitive acts referenced above. Serono's profit margins have increased from approximately 67% in 1995 to approximately 75% in 1999 to approximately 83% in 2001.

COUNT I

ACTUAL MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2)

34. Ferring hereby realleges and incorporates by reference the allegations in paragraphs 1-33.

35. Serono has monopolized the relevant market for certain infertility prescription drug products including the relevant market of gonadotropins through the above-referenced conduct. Serono has dominated the gonadotropin market with resultant market power and the ability to control price and exclude competition in said market.

36. Serono has engaged in actual monopolization of the following relevant markets: the gonadotropin market; the FSH market; the recombinant FSH market; the hCG market; the recombinant hCG market, and certain clusters of said markets. This has been accomplished by the above-referenced predatory acts and by exerting control over the prices of products in the infertility prescription drug markets and by excluding competition from the relevant markets referenced above.

37. Serono has used its dominance and leverage in the above-referenced relevant markets to exclude competitors from other infertility markets such as the FSH/LH market, and the antagonist market.

38. Serono's actual monopolization has resulted in stabilized and/or higher prices for gonadotropin products and has stabilized and/or increased prices in the market for other infertility products, all to the detriment of the consuming public.

39. There are barriers to entry in the infertility prescription drug market because of the large capital expenditures for research and development, as well as the federal regulatory approval process for new prescription drugs. Serono has enhanced these barriers by using the above-referenced predatory acts and practices to block competition.

40. Through the above-referenced acts, Serono has directly and proximately caused damage to the business and property of Ferring, by eliminating Ferring's customers and potential customers, all to the detriment of Ferring's business and property, resulting in Ferring losing sales and profits.

41. All of said above-referenced conduct violates Section 2 of the Sherman Act.

COUNT II

ATTEMPTED MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2)

42. Ferring hereby realleges and incorporates by reference the allegations in paragraphs 1-41.

43. Over the last several years, Serono's market share in the gonadotropin market and other infertility markets has fluctuated due to the presence of recent entrants. To the extent Serono's market power has not been strong enough to actually monopolize said markets, Serono has attempted to recapture market share to effect control over price and to exclude competitors.

44. Serono has attempted to monopolize the market for infertility prescription drug products including the following relevant markets: the gonadotropin market; the FSH/LH market; the hCG market; the FSH market; the GnRH antagonist market, and clusters of said markets.

45. Serono has manifested a specific intent to monopolize the relevant markets identified above.

46. There is a dangerous probability that Serono will successfully monopolize said relevant markets through its use, among other things, of its market power in the markets it is or has been monopolizing.

47. There are barriers to entry in the infertility prescription drug market because of the large capital expenditures for research and development, as well as the federal regulatory approval process for new prescription drugs. Serono has enhanced these barriers by using the above-referenced predatory acts and practices to block competition.

48. Serono's conduct in attempting to monopolize said relevant markets has resulted in stabilized and/or higher prices, all to the detriment of the consuming public.

49. Through the above-referenced acts, Serono has directly and proximately caused damage to the business and property of Ferring, by eliminating Ferring's customers and potential customers, all to the detriment of Ferring's business and property, resulting in Ferring losing sales and profits.

50. All of said above-referenced conduct violates Section 2 of the Sherman Act.

COUNT III

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '067 PATENT

51. Ferring hereby realleges and incorporates by reference the allegations in paragraphs 1-50.

52. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

53. In its Complaint, Serono has alleged that it is the owner of the '067 patent and that Ferring is infringing and/or actively inducing the infringement of the '067 patent. Ferring denies those allegations.

54. Ferring incorporates by reference all affirmative defenses.

55. Serono has wrongly alleged that Ferring is infringing and/or inducing the infringement of the ’067 patent. At all times relevant to this action, Ferring has not and does not infringe, either literally or under the doctrine of equivalents, and/or actively induce the infringement of any valid or enforceable claim of the ’067 patent.

56. By reason of the foregoing, there is an actual and present controversy between Ferring and Serono concerning the non-infringement of the ’067 patent with respect to which Ferring seeks a declaratory judgment in its favor that Ferring has not and does not infringe and/or actively induce infringement of the ’067 patent.

COUNT IV

DECLARATORY JUDGMENT OF INVALIDITY OF THE ’067 PATENT

57. Ferring hereby realleges and incorporates by reference the allegations in paragraphs 1-56.

58. The ’067 patent is invalid and/or unenforceable for failing to comply with Title 35 of the United States Code, including, but not limited to, one or more of the provisions of 35 U.S.C. §§ 101, 102, 103, and 112.

59. By reason of the foregoing, there is an actual and present controversy between Ferring and Serono concerning the invalidity and/or unenforceability of the ’067 patent with respect to which Ferring seeks a declaratory judgment in its favor that the ’067 patent is invalid and/or unenforceable.

COUNT V

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’579 PATENT

60. Ferring hereby realleges and incorporates by reference the allegations in paragraphs 1-59.

61. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

62. In its Complaint, Serono has alleged that it is the owner of the '579 patent and that Ferring is infringing and/or actively inducing the infringement of the '579 patent. Ferring denies those allegations.

63. Ferring incorporates by reference all affirmative defenses.

64. Serono has wrongly alleged that Ferring is infringing and/or inducing the infringement of the '579 patent. At all times relevant to this action, Ferring has not and does not infringe, either literally or under the doctrine of equivalents, and/or actively induce the infringement of any valid or enforceable claim of the '579 patent.

65. By reason of the foregoing, there is an actual and present controversy between Ferring and Serono concerning the non-infringement of the '579 patent with respect to which Ferring seeks a declaratory judgment in its favor that Ferring has not and does not infringe and/or actively induce infringement of the '579 patent.

COUNT VI

DECLARATORY JUDGMENT OF INVALIDITY OF THE '579 PATENT

66. Ferring hereby realleges and incorporates by reference the allegations in paragraphs 1-65.

67. The '579 patent is invalid and/or unenforceable for failing to comply with Title 35 of the United States Code, including, but not limited to, one or more of the provisions of 35 U.S.C. §§ 101, 102, 103, and 112.

68. By reason of the foregoing, there is an actual and present controversy between Ferring and Serono concerning the invalidity and/or unenforceability of the '579 patent with respect to which Ferring seeks a declaratory judgment in its favor that the '579 patent is invalid and/or unenforceable.

COUNT VII

DECLARATORY JUDGMENT THAT THE '579 PATENT AND ALL RELATED PATENTS SUCH AS THOSE IN THIS SUIT, ARE UNENFORCEABLE DUE TO INEQUITABLE CONDUCT

69. Ferring hereby realleges and incorporates by reference the allegations in paragraphs 1-68.

70. In its Complaint, Serono has alleged that it is the owner of the '067 and '579 patents and that Ferring is infringing and/or actively inducing the infringement of these patents. Ferring denies those allegations.

71. These patents are unenforceable because they are part of a family of patents tainted by fraud. The fraud originated with the '402 patent, which is unenforceable because it was obtained through fraudulent and inequitable conduct by the inventor, Georgeanna S. Jones; the attorney prosecuting the patent application, Edward A. Meilman, or anyone else substantively involved in the prosecution of the patent application, because Georgeanna S. Jones, Edward A. Meilman or anyone else substantively involved in the prosecution of the patent application withheld and misrepresented information material to examining the patent application with the intent to deceive or mislead the United States Patent and Trademark Office in violation of their duty of candor as required by 21 C.F.R. §1.56.

72. Georgeanna S. Jones, Edward A. Meilman or anyone else substantively involved in the prosecution of that '402 patent application knew or should have known of at least the following reference(s) which is material to the examination of the '402 patent application: Schoemaker, et al., "Stimulation of follicular growth with "pure" FSH in patients with anovulation and elevated LH levels", Obstetrics and Gynecology Vol. 51, No. 3 p. 270-277 (March 1978).

73. The Schoemaker reference was co-authored by Georgeanna S. Jones.

74. Although Georgeanna S. Jones, Edward A. Meilman or anyone else substantively involved in the prosecution of that '402 patent application knew or should have known of the Schoemaker reference, the reference was withheld from the United States Patent and Trademark Office with the intent to deceive or mislead.

75. In addition to intentionally withholding material information, Georgeanna S. Jones, Edward A. Meilman or anyone else substantively involved in the prosecution of the patent application also misrepresented information material to examination of the '402 patent application, including, at least the following statements made during prosecution of that patent application:

a. "Donini has been cited to show the use of HCG for ovulation induction. The use of HCG to induce ovulation of follicles which have been matured is known. However, the use of HCG to induce ovulation of follicles which have been matured to a course of treatment which involves administering exogeneous FSH in the absence of exogeneous LH is new." Prosecution History, Amendment under Rule 115 dated October 15, 1985 p. 2

b. "Those skilled in the art would not recognize that a reference [in the Seed reference] to the administration of FSH meant the administration of this hormone alone without LH in the absence of an explicit statement in the reference to this effect. Since there is no such statement in Seed, those skilled in the art would understand the reference to administration of FSH on page 23 to mean the administration of FSH together with LH. Prior to the present invention, those skilled in the art did not recognize that exogeneous FSH could be administered in

the absence of exogeneous LH." Amendment under Rule 115 dated October 15, 1985, at p. 3

76. Contrary to the statements made by the applicants, it was well known to those skilled in the art at the time of filing the '402 patent application that exogeneous FSH could be administered in the absence of exogeneous LH. In fact, the published Schoemaker reference disclosed nearly seven years prior to the filing of the '402 patent application that:

> Induction of ovulation with an FSH preparation virtually devoid of LH might therefore reduce the incidence of hyperstimulation in this group. This paper describes our first results with stimulation of follicular growth with pure FSH and subsequent induction of ovulation with hCG in patients with elevated LH levels.

Schoemaker, at 270.

77. The inventor, Georgeanna S. Jones, is a co-author of the Schoemaker reference and knew or should have known that the statements made during prosecution that the administration of FSH in the absence of exogeneous LH is new or was unknown to those skilled in the art prior to the present invention were false. Further, the patent attorney prosecuting the '402 patent application, Edward A. Meilman or anyone else substantively involved in the prosecution of that '402 patent application knew or should have known that the above statements made during prosecution were false.

78. By reason of the foregoing, there is an actual and present controversy between Ferring and Serono concerning unenforceability of the '402 patent and the patents in suit, with respect to which Ferring seeks a declaratory judgment in its favor that the '402 patent and the patents in suit are unenforceable.

COUNT VIII

FALSE ADVERTISING IN VIOLATION OF SECTION 43A OF THE LANHAM ACT, 15 U.S.C. §1125(a)

79. Ferring hereby realleges and incorporates by reference the allegations in paragraphs 1-78.

80. Serono has distributed and promoted promotional brochures for Gonal-F® that contain false and misleading claims. A true and correct copy of the Serono's promotional brochure is attached hereto and incorporated herein as Exhibit 2. Serono's false and misleading claims are material, in that it is likely to influence the purchasing decision of customers of infertility products.

81. In a letter dated June 5, 2002, Ferring wrote to the Food and Drug Administration, Division of Drug, Marketing, Advertising and Communications concerning Serono's false and misleading advertising. A true and correct copy of the June 5, 2002 letter is attached hereto and incorporated herein as Exhibit 3.

82. In a letter dated June 21, 2002, the Food and Drug Administration responded to Ferring's June 5, 2002 letter stating that "[It] has considered [Ferring's] complaint and has determined that it appears to have merit. Thus, we will take an appropriate action as deemed necessary." A true and correct copy of the June 21, 2002 letter is attached hereto and incorporated herein as Exhibit 4.

83. The false and misleading statements in Serono's promotional brochure for Gonal-F® include:

a. statements that Gonal-F® has greater and superior efficacy than similar products;

b. statements that Gonal-F® "Delivers greater patient comfort"; and

c. statements suggesting that Gonal-F® is superior in satisfaction.

84. As a result of Serono's false and misleading statements, consumers have been and are actually confused and deceived into believing that Serono's Gonal-F® production provides superior efficacy, comfort and satisfaction compared to similar products of its competitors, including Ferring. Serono's false and misleading statements also has the tendency to deceive a substantial segment of its audience into believing that Serono's Gonal-F® product provides superior efficacy, comfort and satisfaction compared to similar products of its competitors, including Ferring.

85. Serono has used its false and misleading promotional brochure in the market for gonadotropins to gain an unfair advantage over its competitors.

86. Through the above-referenced acts, Serono has directly and proximately caused damage to the business and property of Ferring, all to the detriment of Ferring's business and property, resulting in Ferring losing sales and profits.

WHEREFORE, Ferring requests that the Court grant the following relief:

A. An injunction enjoining Serono from all anti-competitive conduct;

B. An award of damages incurred by Ferring proximately caused by the anti-competitive conduct of Serono;

C. A tripling of the damages found to be due Ferring;

D. An award of Ferring's reasonable attorneys' fees;

E. Ferring's costs, disbursements, and other expenses;

F. A declaration that Ferring has not and does not infringe or induce infringement of any claim of the '067 patent and/or the '579 patent;

G. A declaration that every claim of the ’067 patent and/or the ’579 patent is invalid and unenforceable;

H. A declaration that no damages are due from Ferring to Serono for any of the acts alleged by Serono in its Complaint;

I. A declaration that the ‘402 patent and the patents in suit are unenforceable due to inequitable conduct.

J. That Serono’s Complaint be dismissed with prejudice;

K. A declaration that Serono’s promotional brochure for its Gonal-F® product is false and misleading;

L. An injunction enjoining Serono from distributing false and misleading statements concerning its Gonal-F® product;

M. An award of damages incurred by Ferring proximately caused by Serono’s false and misleading advertisement; and

N. Any other relief the Court deems proper.

Dated this 16th day of August, 2004.

FERRING PHARMACUETICALS, INC.
By its attorneys,

/s/Erin D.E. Joffre_____
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CERTIFICATE OF SERVICE

I hereby certify that I caused a true copy of the above document to be served upon the attorney of record for each other party by mail on August 16, 2004.

_____**/s/Erin D.E. Joffre**_____